

UNITED STATES DISTRICT COURT  
DISTRICT OF MASSACHUSETTS

IN RE NEW ENGLAND COMPOUNDING )  
PHARMACY, INC. PRODUCTS LIABILITY )  
LITIGATION )  
\_\_\_\_\_ )

MDL No. 2419  
Dkt. No 1:13-md-2419 (RWZ)

THIS DOCUMENT RELATES TO: )

All Cases )  
\_\_\_\_\_ )

**Memorandum in Support of Omnibus Motion to Compel the PSC to Respond to  
Discovery Served by the Tennessee Clinic Defendants  
and Motion to Deem Requests Admitted**

Defendants Saint Thomas Outpatient Neurosurgical Center, LLC; Howell Allen Clinic, a Professional Corporation; John Culclasure, MD; Debra Schamberg, RN, CNOR; Specialty Surgery Center, PLLC; Kenneth R. Lister, MD; and Kenneth Lister, MD, PC (collectively "Tennessee Clinic Defendants") hereby move the Court, pursuant to Fed. R. Civ. P. 26, 33, 34, 36, and 37, to compel the PSC to respond to specific discovery requests served by the Tennessee Clinic Defendants and/or deem admitted specific requests for admissions.

To assist the Court, the Tennessee Clinic Defendants attach:

Exhibit 1: Outline of the categories of RFAs, ROGs, and RFPs at issue as they are organized in this brief

Exhibits 2-14: Disputed discovery responses organized by objection and corresponding to the sections of this brief

Exhibit 15: All disputed RFAs in numerical order

Exhibit 16: All disputed ROGs in numerical order

Exhibit 17: All disputed RFPs in numerical order

## **BACKGROUND AND INTRODUCTION**

Dates of Service and Responses: On November 7, 2014, the Tennessee Clinic Defendants served the PSC with one set of requests for admissions, interrogatories, and requests for production on behalf of the STOPNC defendants<sup>1</sup> and a virtually identical set of discovery from the SSC defendants.<sup>2</sup> On December 23, 2014, the PSC responded to these sets of discovery with almost identical responses. This motion references the STOPNC defendants' discovery requests for simplicity and efficiency's sake. Once the Court rules on the motion, the parties should be able to agree on how it will apply to the SSC defendants' discovery responses.

Requests for Admissions: The STOPNC defendants served 142 requests for admissions in an attempt to narrow the issues. Of the 142 requests for admission, the PSC refused to respond to approximately 80. For the roughly 50 that the PSC responded to, most were accompanied by some type of improper qualification or objection.

Interrogatories: The STOPNC defendants served 13 interrogatories. The PSC objected to *every single* interrogatory, and, construing the PSC's responses most favorably to them, provided substantive responses to just five of the 13 interrogatories.

Requests for Production: The Defendants served the PSC with nine requests for production. Again, the PSC objected to virtually every request and produced *two* pages of documents. Additionally, the PSC never produced a privilege log as required by MDL Order No. 9,<sup>3</sup> despite raising several privilege objections.

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<sup>1</sup> Saint Thomas Outpatient Neurosurgical Center, LLC; Howell Allen Clinic, a Professional Corporation; John Culclasure, MD; and Debra Schamberg, RN, CNOR.

<sup>2</sup> Specialty Surgery Center, PLLC; Kenneth R. Lister, MD; and Kenneth Lister, MD, PC.

<sup>3</sup> Dkt. 1425.

Meet and Confer Status:<sup>4</sup> On May 6, 2015, Matt Cline for the Tennessee Clinic Defendants and Ben Gastel conferred via phone for over an hour. Progress was made toward reaching agreement on several areas, but significant areas of dispute remain. The parties agreed that the Tennessee Clinic Defendants would proceed with filing the instant motion to ensure that it is fully-briefed by the May 28 hearing, given the current deadline for completion of common discovery. The parties also agreed to continue to work toward resolution prior to the May 28 hearing before Magistrate Boal. Either in their briefing or at argument, the parties will inform the Court of any additional areas of agreement reached prior to the hearing.

### **LAW AND ARGUMENT**

These Defendants will not rehash the well-known general law on discovery here, as the Court is well-aware of the basic tenets. The Defendants do note that, in its Order on Motions to Quash and Objections to Subpoenas,<sup>5</sup> the Court recognized that the limits set forth in Rule 26 must be “construed broadly to encompass any matter that bears on, or that reasonably could lead to other matters that could bear on, any issue that is or may be in the case.”<sup>6</sup> Additionally, “[t]he Federal Rules of Civil Procedure require parties to respond to discovery requests in good faith.”<sup>7</sup>

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<sup>4</sup> On April 9, 2015, the Defendants sent the PSC a letter outlining the deficiencies in its discovery responses and requesting a meet and confer within the 14-day period set by Local Rule 37.1. The letter is attached as Exhibit 18. The PSC failed to respond within the seven days permitted by the Local Rule (which is grounds for allowance of the motion). On April 23, the Defendants reached out to the PSC again, and the PSC offered to meet and confer on May 6 or May 7. On May 1, the PSC sent the Defendant the response letter attached as Exhibit 19 addressing the Plaintiffs’ position on the deficient discovery responses.

<sup>5</sup> Dkt. 572.

<sup>6</sup> *Oppenheimer Fund, Inc. v. Sanders*, 437 U.S. 340, 351 (1978).

<sup>7</sup> *Puma AG Rudolf Dassler Sport v. Payless ShoeSource, Inc.*, No. CIV.A.06-11943-RGS, 2008 WL 686592, at \*1 (D. Mass. Mar. 14, 2008).

The Plaintiffs here have plainly failed to do so. However, at the same time as the Plaintiffs obstruct the Defendants' attempt to obtain information necessary for trial, the Plaintiffs insist that discovery can be completed in time for an expedited trial date. These cases cannot be fairly tried until all parties are on equal footing in terms of the information and discovery available to them.

Reproducing all of the PSC's deficient, form objections and corresponding discovery requests in the text of this brief would exceed the 20-page limit for motion practice, and would leave no space for analysis. Thus, the Defendants have categorized the deficient responses in this brief by type of request (RFAs, ROGs, RFPs) and then by general nature of the objection.<sup>8</sup>

#### **1. Requests for Admissions ("RFAs")**

"Admissions are sought, first to facilitate proof with respect to issues that cannot be eliminated from the case, and secondly, to narrow the issues by eliminating those that can be."<sup>9</sup> The Defendants' RFAs are designed to serve both purposes. However, the PSC refused to admit or deny more than 80 of the 142 RFAs. This is plainly a refusal to participate in the discovery process in good faith.

##### **a. The PSC should be compelled to answer all RFAs to which they object by saying that the RFA seeks a legal conclusion.** **[RFAs 4-18, 20, 23-24, 26-28, 29, 31, 74-79, 90-92, 125, 130]**

The Plaintiffs objected to 34 RFAs on the grounds that they supposedly call for a legal conclusion.<sup>10</sup> These objections are improper for several reasons.

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<sup>8</sup> See Exhibit 1 for an outline of the categories, which should help the Court organize the categories of deficient responses at issue.

<sup>9</sup> Advisory Committee Notes, 1970 Amendment to FED. R. CIV. P. 36.

<sup>10</sup> For example:

**RFA 5:** NECC and its owners, managers, employees, and agents breached their duty to the Plaintiffs.

First, impermissible RFAs that seek a legal conclusion are those that involve “abstract questions of law...unrelated to the facts of the case.”<sup>11</sup> The RFAs at issue do not require pure, abstract legal conclusions. They require *the application of law to the facts of these cases*, which is expressly permitted by Rule 36. The Advisory Committee Notes recognize that RFAs involving mixed questions of law and fact are particularly useful in narrowing the issues for trial.<sup>12</sup> The examples in the Notes are very similar to the RFAs at issue here (*e.g.*, whether an employee (fact) was acting “within the course and scope of his employment” (law)).<sup>13</sup>

Further, the two cases cited by the PSC in support of this objection are clearly inapplicable.

The three RFAs at issue in *Iantosca v. Benistar Admin Servs., Inc.*<sup>14</sup> did not ask the respondent to apply law to facts; they required abstract interpretation of various statutory provisions, without asking for any application to the facts of the case.<sup>15</sup> The case is inapposite.

And, *In re: Tobkin*<sup>16</sup> offers only a two-sentence aside about whether a party could rely on the admission by the Florida Bar Association that it was not a governmental agency. It engages in no meaningful analysis of the issue.

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**Response:** Plaintiffs object to the extent that this RFA requires Plaintiffs to admit to a legal conclusion which is not a permissible use of Rule 36 RFAs. *See, e.g., Iantosca v. Benistar Admin. Servs., Inc.*, Case No. 08-11785, 2012 US Dist. LEXIS 7896 (D. Mass. 2012); *In re Tobkin*, 578 Fed. Appx. 962 (11th Cir. 2014).

<sup>11</sup> *Brown v. Montoya*, No. CIV 10-0081 JB/ACT, 2013 WL 1010390, at \*23 (D.N.M. Mar. 8, 2013) (recognizing that the rules do not allow requests for admission unrelated to the facts of the case but do allow requests seeking application of law to the facts of the case).

<sup>12</sup> Advisory Committee Notes, 1970 Amendment to FED. R. CIV. P. 36.

<sup>13</sup> *Id.*

<sup>14</sup> Case No. 08-11785, 2012 U.S. Dist. LEXIS 7896 (D. Mass. 2012).

<sup>15</sup> The *Iantosca* RFAs at issue were RFAs 6, 7, and 9, which are attached to this motion as Exhibit 20.

<sup>16</sup> 578 Fed. Appx. 962 (11th Cir. 2014).

Further subcategorization of the “legal conclusion” objections illustrates their inappropriateness:

- i. RFAs that seek admissions regarding duty, breach, and causation pertaining to other parties are appropriate requests for an application of law to fact and should be answered. [RFAs 4-18, 23-24, 26-28, 75-78]<sup>17</sup>**

Twenty-four (24) of these RFAs, ask the PSC to admit that other parties<sup>18</sup> and nonparties<sup>19</sup> (1) owed a duty to the Plaintiffs, (2) breached a duty to the Plaintiffs, and (3) caused the Plaintiffs' injuries.

As a practical matter, most of these requests simply ask the PSC to admit allegations the Plaintiffs made in their own complaints.

For instance, in the *Reed* complaint<sup>20</sup> (one of the cases the PSC contends should be tried first), the Plaintiff alleges that Medical Sales Management (“MSM”) “owed a duty to Plaintiff to comply with existing standards of care, and to exercise due care[,]” as the “designer, tester, compounder, seller, marketer and/or distributor of consumer products” in this case.<sup>21</sup> Likewise, RFA 7 asks the PSC to admit that MSM owed a duty to the Plaintiffs to exercise reasonable care when marketing and selling NECC's products.

The Defendants ask the PSC to simply admit something it has already alleged as true, but the PSC refuses.<sup>22</sup> This is the type of gamesmanship that should not be tolerated.

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<sup>17</sup> Attached as Exhibit 2.

<sup>18</sup> NECC and the Affiliated and National Defendants. See RFAs 4-18.

<sup>19</sup> The FDA and Massachusetts Board of Pharmacy.

<sup>20</sup> Case No. 1:13-cv-12565, Dkt. 1, excerpt attached as Exhibit 21.

<sup>21</sup> *Reed* MDL Compl. ¶ 196, excerpt attached as Exhibit 21.

<sup>22</sup> Once the PSC has settled with these parties, the PSC wishes to believe they do not exist and bear no responsibility.

The RFAs at issue here are not pure questions of law.<sup>23</sup> The Defendants do not ask that the PSC admit the existence of a generic legal duty in a vacuum, absent any factual underpinnings. They request that the PSC admit that the parties in this case, based on the facts reasonably known at this time, owed a legal duty to the Plaintiffs. This is an appropriate request for an application of law to fact.<sup>24 25</sup>

**ii. RFAs that ask about public agencies' duties are appropriate requests for an application of law to fact and should be answered.  
[RFAs 31, 74, 79, 90-92]<sup>26</sup>**

Similarly, six of these RFAs ask the PSC to admit that various regulatory agencies (most of which issued licenses to NECC) had regulatory authority over NECC, and could have shut NECC down prior to the outbreak.<sup>27</sup> Again, these requests ask for an application of law to fact – whether the agency had regulatory authority (law) over

<sup>23</sup> See *Brown*, No. CIV 10-0081 JB/ACT, 2013 WL 1010390, at \*23 (recognizing that the rules do not allow requests for admission unrelated to the facts of the case but do allow requests seeking application of law to the facts of the case).

<sup>24</sup> *Brown*, No. CIV 10-0081 JB/ACT, 2013 WL 1010390, is instructive. There, the New Mexico district court ordered the party to respond to RFAs designed to establish that the defendant had a certain duty:

Here, the Plaintiffs' RFAs that ask whether the particular Defendant's duty or authority includes ensuring that the Defendant's agency's, office's, or political subdivision's "policies are in compliance with relevant state and federal laws, including the Fourteenth Amendment to the United States Constitution," seek to apply the law to the facts of the case. They are not requests for pure matters of law "unrelated to the facts of the case."...[T]he RFAs here are...trying to determine, factually, if individual Defendants are individually involved in, or responsible for, ensuring their office's compliance with laws and the Constitution. These RFAs are not asking whether the Constitution's Fourteenth Amendment protects an individual's privacy rights from state infringement. Nor are they asking if the New Mexico Constitution's Due Process Clause protects and individual's privacy rights to the same extent as the United States Constitution's Due Process Clause. They are not a question taken from the Multistate Bar Examination in true/false form, asking the Defendants to admit the truth of the bar exam question. Rather, because at issue in this case, which sets forth a claim under 42 U.S.C. § 1983, is whether the policies of the Defendants' offices violated the Plaintiffs' constitutional rights, these RFAs are not unrelated to the case.

*Brown*, 2013 WL 1010390, at \*24.

<sup>25</sup> See also *AngioScore, Inc. v. TriReme Med., Inc.*, No. 12-cv-03393-YGR (JSC), 2014 WL 7188779, at \*7 (N.D. Cal. 2014) ("A request for admission calls for a legal conclusion when it purports to require a party to admit, for example, that a statute or regulation imposes a particular obligation. In contrast, a request which asks how a particular source of a legal obligation applies to a given set of facts is permissible.") (internal citations omitted).

<sup>26</sup> Attached as Exhibit 3.

<sup>27</sup> RFA 74 involves a similar issue with respect to the FDA's ability to regulate ARL.

NECC (fact). The requests do not ask for an abstract interpretation of law unrelated to the facts of the case. These are proper RFAs, and they should be answered.<sup>28</sup>

**iii. The RFA that asks for admission that NECC violated the FDA's compliance guide is proper and should be answered.  
[RFA 29]<sup>29</sup>**

Likewise, RFA 29 asks the PSC to admit that NECC violated the FDA's Compliance Policy Guidance on Compounding<sup>30</sup> in three specific ways, clearly constituting application of law to fact.<sup>31</sup>

**iv. RFAs that ask for application of the standard of care, or whether a specific act was reasonably foreseeable based on the case-specific facts are proper and should be answered.  
[RFAs 20, 125, 130]<sup>32</sup>**

RFAs 20 and 125 seek admissions regarding the application of the appropriate standard of care to the facts of this case. And, RFA 130 asks the PSC to admit that fungal contamination of NECC's medications was not reasonably foreseeable to these Defendants. These ask for opinions or law to be applied to the facts of this case, which is expressly permitted by Rule 36.<sup>33</sup>

<sup>28</sup> See *Brown*, 2013 WL 1010390, at \*24-\*25 (ordering party to respond to RFAs seeking admission that government office had a duty to implement certain tasks or policies at issue in the case; "[t]he Plaintiffs' requests whether an individual Defendant's duty or authority includes implementing certain tasks or policies at issue in the case, like the RFAs asking if the Defendant is charged with ensuring his or her department's compliance with law, are not asking a pure question of law without regard to the facts. Rather, these RFAs also ask the Defendants to admit or deny a question designed to narrow down whether the particular individual defendant is responsible — factually — for implementing certain policies and tasks, and designed to 'expedite [the] trial by establishing as true certain material facts of a case without the necessity of formal proof at trial.'" (internal citation omitted).

<sup>29</sup> Attached as Exhibit 4.

<sup>30</sup> The Compliance Policy Guidance in place during the relevant time period is available here: [http://www.fda.gov/ohrms/dockets/98fr/02d-0242\\_gdl0001.pdf](http://www.fda.gov/ohrms/dockets/98fr/02d-0242_gdl0001.pdf).

<sup>31</sup> See *AngioScore*, No. 12-cv-03393-YGR (JSC), 2014 WL 7188779, at \*7 ("[a] request for admission calls for a legal conclusion when it purports to require a party to admit, for example, that a statute or regulation imposes a particular obligation. In contrast, a request which asks how a particular source of a legal obligation applies to a given set of facts is permissible.") (internal citations omitted).

<sup>32</sup> Attached as Exhibit 5.

<sup>33</sup> See, e.g., *Tustin v. Motorists Mut. Ins. Co.*, No. 5:08-CV-111, 2009 WL 3335060, at \*5-\*7; 10-12 (N.D. W.V. 2009) (holding requests for admission asking the party to admit (1) that certain injuries occurred as a proximate result of the accident; (2) that certain medical bills were incurred as a proximate result of the



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“Requests for Admission are not objectionable even if they require opinions or conclusions of law, as long as the legal conclusions relate to the facts of the case.”<sup>34</sup> The PSC attempts to use a form “legal conclusion” objection to avoid responding to requests for admission framed to specifically ask for application of law to fact. The PSC should be ordered to substantively respond (either admit, deny, or explain why they cannot admit or deny) the RFAs identified above because the “legal conclusion” objection is improper; or, the Court should deem these requests admitted.

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**b. The PSC should be compelled to respond to all RFAs to which they object based on information being in possession of third parties. [RFAs 21-22, 34, 42, 45, 47, 49, 51, 53-57, 60-65, 69-72, 80-89, 94, 108, 110, 114-125, 127, 131-140]**

The PSC objected to 59 of these Defendants’ RFAs either because (1) the information necessary to respond was not in the possession of the Plaintiffs or (2) the Plaintiffs were not able to respond after making a reasonable inquiry.

Fed. R. Civ. P. 36 does not permit parties to object to RFAs solely because the information necessary to respond is not in the possession of the respondent.<sup>35</sup> “[A] response that fails to admit or deny a proper request for admission does not comply

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accident; (3) that the defendant handled the underinsurance claim in accordance with its general business practices for that state at that time; and (4) that the defendant believes its employees acted in accordance with its general training, policies, and established practices, were permissible because the requests asked for applications of law or opinion to fact).

<sup>34</sup> *Duchesneau v. Cornell Univ.*, No. 08-4856, 2010 WL 4117753, at \*4 (E.D. Pa. 2010) (internal citations and quotations omitted).

<sup>35</sup> See Fed. R. Civ. P. 36; *Jones v. Zimmer*, No. 2:12-cv-01578-JAD-NJK, 2014 WL 6772916, at \*6 (D. Nev. 2014) (“[t]he Court takes judicial notice of the fact that, to the extent Defendant does not already have easy access to it, AR 707 is available publicly online....Given that Defendant (1) knew the statement at issue and (2) had ready access to AR 707, it is clear that the information necessary to admit or deny the request for admission was already known or readily obtainable at the time of the initial response. There was no basis for Defendant to respond to this request for admission by asserting a lack of sufficient information.”).

with the requirements of Rule 36(a) if the answering party has not, in fact, made 'reasonable inquiry,' or if information 'readily obtainable' is sufficient to enable him to admit or deny the matter."<sup>36</sup>

What is a reasonable inquiry depends on the facts of each case.<sup>37</sup> Courts are encouraged to require parties to respond to RFAs where the party can make the necessary inquiry without extraordinary expense or effort.<sup>38</sup> A party cannot avoid responding to the request based on an overly technical reading of the request where the purpose and significance of the request is reasonably clear.<sup>39</sup>

**i. RFAs that ask the PSC to admit various events in NECC's regulatory history as documented in readily-available sources are appropriate and should be answered.  
[RFAs 47, 49, 51, 53-57, 60-65, 69-72, 81-89]<sup>40</sup>**

Twenty-seven (27) of these 59 RFAs detail NECC's factual history with the FDA and Massachusetts Board of Pharmacy.<sup>41</sup> The information necessary to admit or deny

<sup>36</sup> *Asea, Inc. v. S. Pac. Transp. Co.*, 669 F.2d 1242, 1247 (9th Cir. 1981).

<sup>37</sup> *Al-Jundi v. Rockefeller*, 91 F.R.D. 590, 593 (W.D. N.Y. 1981).

<sup>38</sup> *Al-Jundi*, 91 F.R.D. at 594.

<sup>39</sup> *U.S. v. Los Angeles County*, 235 F.R.D. 675, 684 (E.D. Ca. 2006) ("When the purpose and significance of a request are reasonably clear, courts do not permit denials based on an overly-technical reading of the request.") (internal citations omitted).

<sup>40</sup> Attached as Exhibit 6.

<sup>41</sup> For example:

**RFA 84:** Between 2002 and 2004, the Mass. BoP received complaints from the boards of pharmacy for the states of Texas, South Dakota, Iowa, and Wisconsin reporting that NECC was illegally soliciting out-of-state prescriptions for office use, but the Mass. BoP allowed NECC to continue to compound medications.

**Response:** Plaintiffs object to this RFA as it is overly broad and unduly burdensome in that it requires Plaintiffs to review all communications from the referenced boards of pharmacy to the Massachusetts Board of Pharmacy during the relevant time period. Plaintiffs state that Plaintiffs' counsel made reasonable inquiry regarding the matters stated in this request, and the information known or readily obtainable by the Plaintiffs' Counsel is insufficient to enable the Plaintiffs' counsel to admit or deny this request. The information necessary to respond to this RFA is in the possession of third parties, and Plaintiffs have made a reasonable inquiry as to the documents within its possession, and such information is insufficient to admit or deny. Further, Rule 36 does not impose upon Plaintiffs the duty to investigate or obtain documents within the possession of third parties in order to obtain information necessary to respond to an RFA. See e.g., *Henry Champlain Enterprises, Inc.*, 212 F.R.D. 73 (N.D. New York 2003) (collecting cases and authorities). Further, to the extent this RFA is meant to reference documents referenced in Exhibit C, those documents do not come from the "boards of pharmacy" from the states identified, but

these RFAs was obtained from documents released online by the FDA and Massachusetts Board of Pharmacy.<sup>42</sup> Documents available to the public online are certainly “readily obtainable.”<sup>43</sup>

It is inconceivable that the PSC would not have obtained and reviewed these documents to develop its case against NECC and the Insiders. In fact, several of the RFAs mirror the allegations in the original suits filed against the STOPNC defendants, demonstrating that the Plaintiffs possessed these documents as early as February 2013.<sup>44</sup>

Regardless, when the RFAs were served, the Defendants provided the PSC with a copy of a Congressional report summarizing the FDA’s history with NECC.<sup>45</sup> The PSC’s refusal to admit these noncontroversial facts reflects its refusal to participate in good faith in discovery.

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rather come from individual pharmacists. Therefore, to the extent that this is meant to reference those complaints, this RFA is denied.

<sup>42</sup> The FDA documents are available here:

<http://www.fda.gov/AboutFDA/CentersOffices/OfficeofGlobalRegulatoryOperationsandPolicy/ORA/ORAElectronicReadingRoom/ucm325828.htm>.

The Massachusetts Board of Pharmacy documents are available here:

<http://web.archive.org/web/20130302071039/http://www.mass.gov/eohhs/provider/licensing/occupational/pharmacy/necc-application-inspection-and-investigation-documents.html>.

<sup>43</sup> *Jones*, No. 2:12-cv-01578-JAD-NJK, 2014 WL 6772916, at \*6 (“[t]he Court takes judicial notice of the fact that, to the extent Defendant does not already have easy access to it, AR 707 is available publicly online.... Given that Defendant (1) knew the statement at issue and (2) had ready access to AR 707, it is clear that the information necessary to admit or deny the request for admission was already known or readily obtainable at the time of the initial response. There was no basis for Defendant to respond to this request for admission by asserting a lack of sufficient information.”).

<sup>44</sup> *Compare* state court *Reed* Compl. ¶ 26 (“...in April 1999, just 10 months after [NECC] obtained its license[,] [t]he Massachusetts Board of Registration in Pharmacy filed a complaint asserting that NECC was including blank prescriptions in its solicitation to doctors, in violation of state law.”) (excerpt attached as Exhibit 22) *with* RFA 81 (“In 1999, after receiving a report that NECC had violated Mass. BoP regulations by providing blank prescription pads in its solicitations to doctors, the Mass. BoP initiated an investigation....”).

<sup>45</sup> The Congressional report is available online here:

<http://docs.house.gov/meetings/IF/IF02/20130416/100668/HHRG-113-IF02-20130416-SD101.pdf>.

- ii. RFAs that ask the PSC to admit information readily available in online governmental sources or other sources provided to the PSC are proper and should be answered.

[RFAs 21-22, 34, 94, 108, 110, 114-125, 127, 131-140]<sup>46</sup>

Likewise, the PSC refused to respond to multiple RFAs even though these Defendants provided a citation to the relevant information. These RFAs should be deemed admitted.

For example, the Defendants provided the PSC with a copy of an official survey of a representative sample of acute-care hospitals participating in Medicare about the use of compounded medication conducted by the United States Office of the Inspector General.<sup>47</sup> The Defendants requested that the PSC admit several facts from the report.<sup>48</sup> An example:

**RFA 121:** Despite the survey taking place after the 2012 fungal meningitis outbreak, “few hospitals (11 of 236) in [the] sample reported problems with product contamination....”

The PSC refused to admit this fact from the survey, essentially saying that the information to respond to this request is in the possession of third-parties.

The Defendants provided the PSC with a copy of the survey, which is an official government publication readily obtainable online. The PSC can quibble with the methodology of the survey or the admissibility of its findings. However, the objections to RFAs taken directly from information in the official government survey are improper.<sup>49</sup>

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<sup>46</sup> Attached as Exhibit 7.

<sup>47</sup> The OIG report is available online here: <https://oig.hhs.gov/oei/reports/oei-01-13-00150.pdf>.

<sup>48</sup> RFAs 114-22.

<sup>49</sup> Interestingly, the Plaintiff in the *Reed* complaint used the same tactic, asking the Defendants to admit that, “[i]n 2006, the FDA conducted a survey of compounded drug products. They collected third-six samples from compounding pharmacies across the United States during unannounced visits. Twelve of the 36 samples (33%) failed analytical testing.” *Reed* MDL Compl. ¶ 114, excerpt attached as Exhibit 21. Now, they refuse to answer RFAs styled the same way.

Like the refusal to accept the results of the OIG survey,<sup>50</sup> the PSC also refused to admit facts taken from readily-available, public sources, hiding behind the form objection that the information is within the possession of third parties. Examples include:

- The PSC refused to admit the median response time for FOIA requests to the FDA despite the fact that the information was included with the RFAs and available on the FDA's website.<sup>51</sup>
- The PSC refused to admit that the FDA's statutory authority to regulate compounding pharmacies did not change between September 2012 and October 2013, asserting that the admission would require the PSC to review every bill passed by Congress during that time period.<sup>52</sup> This objection is ridiculous. The PSC merely needs to check to see when the Food Drug and Cosmetic Act was last amended to admit or deny this RFA. As the PSC well knows, the FDCA was amended in November 2013 in response to the fungal meningitis outbreak, and the amendment was widely publicized.<sup>53</sup>
- The PSC refused to admit the number of Warning Letters issued by the FDA each year from 2006 to 2012 even though that information is publicly available on the FDA website.<sup>54</sup>
- The PSC refused to admit that drug manufacturers use compounding pharmacies for medications in clinical trials in the face of citations to websites for two different compounding pharmacies who provide those services.<sup>55</sup>
- The PSC refused to admit the release date for the ASHP Contractor Assessment Tool referenced in the Master Complaint, even after the Defendants sent the PSC a citation to the dated press release establishing this fact.<sup>56</sup>
- The PSC refused to admit that the ASHP classified NECC and Ameridose as "generic pharmaceuticals" exhibitors at the ASHP conference in December 2011 even though the Defendants provided a citation to the ASHP's exhibitor directory that establishes this fact.

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<sup>50</sup> Which effectively disproves the PSC's entire theory by establishing that the vast majority of hospitals did not conduct the type of due diligence the PSC says was the standard of practice.

<sup>51</sup> RFAs 21-22.

<sup>52</sup> RFA 34.

<sup>53</sup> <http://archive.tennessean.com/article/20131118/NEWS07/311180062/Meningitis-outbreak-Bill-regulate-large-compounders-ready-Obama>.

<sup>54</sup> RFA 94.

<sup>55</sup> RFA 110.

<sup>56</sup> See RFA 123 and letter attached as Exhibit 18 with cite to press release.

- The PSC refused to admit the number of customers who purchased various medications from NECC.<sup>57</sup> This objection is particularly egregious in light of the fact that the FDA and CDC have both published lists of NECC's customers, and the PSC relied on, and reproduced, one of those lists in the Master Complaint.<sup>58</sup>

**iii. RFAs asking the PSC to admit what information was publicly available prior to the outbreak are appropriate and should be answered.**

**[RFAs 42, 45, 80]<sup>59</sup>**

The Plaintiffs contend that, if the Defendants had done the appropriate level of due diligence prior to purchasing from NECC, they would have found information regarding NECC's regulatory history that would have prompted them to purchase medication elsewhere.<sup>60</sup> Thus, the Defendants served requests for admissions aimed at eliminating from contention what was and was not publicly available prior to the meningitis outbreak.<sup>61</sup>

**RFA 80:** Prior to September 18, 2012, a search on the Mass. BoP website for regulatory actions against NECC, Barr Cadden, Lisa Cadden, and/or Glenn Chin would have revealed no disciplinary actions.<sup>62</sup>

The PSC refused to respond, generally claiming that the information necessary to respond is not readily obtainable. The PSC cannot be permitted to claim that information was available to the Defendants while simultaneously claiming that the

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<sup>57</sup> RFAs 131-140.

<sup>58</sup> 2<sup>nd</sup> Am. Master Compl. ¶ 22; CDC List - <http://www.cdc.gov/hai/outbreaks/meningitis-facilities-map.html>; FDA Lists - <http://www.fda.gov/downloads/Drugs/DrugSafety/FungalMeningitis/UCM325466.pdf>; <http://www.fda.gov/downloads/Drugs/DrugSafety/FungalMeningitis/UCM325467.pdf>.

<sup>59</sup> Attached as Exhibit 8.

<sup>60</sup> 2<sup>nd</sup> Am. Master Compl. ¶¶ 192-93.

<sup>61</sup> RFAs 42 and 80.

<sup>62</sup> See Office of Edward Markey, Compounding Pharmacies, Compounding Risk at pp. 3-4 (Oct. 29, 2012), available at [http://www.snmhi.org/files/docs/Compounding%20Pharmacies%20-%20Compounding%20Risk%20FINAL\\_0\\_1382017898361\\_1.pdf](http://www.snmhi.org/files/docs/Compounding%20Pharmacies%20-%20Compounding%20Risk%20FINAL_0_1382017898361_1.pdf) (last visited Oct. 8, 2014) (citation included in original RFA).

information is not readily obtainable. The PSC should be compelled to respond to these RFAs, or they should be deemed admitted.

**c. RFAs that ask the PSC to admit that Teva, Sandoz, and Pfizer manufactured methylprednisolone acetate should be deemed admitted. [RFAs 95, 101, 107]<sup>63</sup>**

There are three FDA-registered drug companies that manufacture methylprednisolone acetate (“MPA”), Teva, Sandoz, and Pfizer. The Defendants asked the Plaintiffs to admit this non-controversial fact, but the Plaintiffs either refused to admit these facts or qualified their admission. The PSC’s position is particularly untenable because all three companies have produced data in this litigation showing that they manufacture MPA. These RFAs should be deemed admitted.

**2. Interrogatories (“ROGs”) and Requests for Production (“RFPs”)**

The Tennessee Clinic Defendants served only 13 interrogatories and nine requests for production on the PSC. The PSC refused to respond to all but five of the interrogatories and produced a total of two one-page documents in response to the requests for production.

**a. The PSC should be compelled to identify the factual basis for its denials of RFAs as requested by ROG 1 and RFP 1. [ROG 1; RFP 1; RFAs 1-2, 39, 41, 66, 67, 107, 113]<sup>64</sup>**

The first ROG and RFP ask the Plaintiffs to provide the factual basis for any denials or qualifications of admissions to RFAs. Of note, the PSC served an identical interrogatory on the Defendants, and the Defendants responded. The Plaintiffs failed to do so for several RFAs. For example:

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<sup>63</sup> Attached as Exhibit 9.

<sup>64</sup> Attached as Exhibit 10.

**RFA 1:** The Health Care Procedure Coding System (“HCPSCS”) code, J1040, existed in 2012 for billing third-party payors and/or patients separately for the steroid administered during epidural steroid injections.

**RESPONSE:** Admitted that HSPCS code J1040 existed in 2012 for billing purposes and for providing additional detail about a procedure. Denied to the extent that the RFA implies that the use of such code would indicate and/or lead to a separate payment for the steroid administered during epidural steroid injections.

There is only one billing code a health care provider can use to bill separately for methylprednisolone acetate used during an injection, J1040. The PSC should be compelled to explain the factual basis for this and similar denials or qualifications.

- b. The PSC should be compelled to answer ROGs and RFPs asking for information and documents supporting Plaintiffs’ claims against settling Defendants.**  
**[ROGs 4, 10; RFPs 3, 5, 6, 8]<sup>65</sup>**

The Defendants served several interrogatories and requests for production seeking information supporting the Plaintiffs’ (now settled) claims against NECC, the Affiliated Defendants, and National Defendants. These requests seek information or documents supporting the Plaintiffs’ claims that these co-defendants acted wrongfully and caused injury.

Rule 26 permits discovery of any non-privileged information relevant to *any party’s* claim or defense.<sup>66</sup> Information establishing the fault of NECC, the Affiliated Defendants, and the National Defendants is relevant to both claims in the case (they are still co-defendants, with active allegations against them) and defenses in the case (comparative fault claims). Thus, the information is discoverable.

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<sup>65</sup> Attached as Exhibit 11.

<sup>66</sup> FED. R. CIV. P. 26.



Furthermore, the purpose of discovery is to facilitate the mutual exchange of information.<sup>67</sup> A party cannot withhold non-privileged information that is discoverable.<sup>68</sup>

The PSC objects to answering these interrogatories, saying that it need not produce information that it does not intend to use (ROG 4) and unilaterally declaring that GDC's<sup>69</sup> fault is not at issue (ROG 10). The PSC offers a litany of form objections to the RFPs on the same topics and also states that all the documents are available on the document repository.

As noted above, the information is discoverable. The PSC should be compelled to respond to ROG 4 and ROG 10. Secondly, because neither the document requests sent to the settling parties nor the settling parties' written responses are on the repository, these Defendants have no way of knowing what has actually been informally produced to the repository. They are simply faced with a voluminous mound of electronic documents, none of which correspond to a particular request made by these Defendants. It is impossible to know whether the documents on the repository satisfy the Defendants' requests and, if they do, *which* documents satisfy *which* request. Simply responding to RFPs with "see documents on the repository"<sup>70</sup> is not a sufficient, responsive answer, particularly when it is clear that many relevant documents in the PSC's possession are *not* on the repository.<sup>71</sup>

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<sup>67</sup> *Hickman v. Taylor*, 329 US 495, 507 (1947) ("Mutual knowledge of all relevant facts is essential to proper litigation.").

<sup>68</sup> FED. R. CIV. P. 26(b)(1) ("Parties may obtain discovery of any nonprivileged matter that is relevant to any party's claim or defense....").

<sup>69</sup> The NECC-related company that owned the premises where NECC compounded the medications.

<sup>70</sup> Response to RFP 8 ("Subject to and without waiving these objections, the PSC states that responsive documents in its possession, custody, or control are located on the U.S. Legal Document Repository and the Rust/Omni Document Repository.").

<sup>71</sup> ARL produced some 28,000 documents to the PSC more than two years ago that were first uploaded to the repository within the last month.

The PSC should be compelled to respond to these interrogatories and requests for production. If the PSC believes that some of the documents are privileged, it can redact privileged information and produce a privilege log as required by MDL Order No. 9.

**c. The PSC's objections to ROGs as "contentious" are improper, and the ROGs should be answered.**  
**[ROGs 2, 3, 8, 11, 13]<sup>72</sup>**

The PSC objected to four of these Defendants' interrogatories on the ground that they are "contentious" and do not need to be answered until the close of discovery.

Contention interrogatories seek to discover the factual basis for the allegations raised in the complaint, answer, or counterclaim.<sup>73</sup> Contention interrogatories ask a party to state its contentions, to provide the factual basis for its claims, or to explain how the law applies to the factual basis of the claims.<sup>74</sup>

First, ROG 2 is not a contention interrogatory. It asks for identification of any customer of NECC who performed the due diligence that the complaint alleges was required. It does not seek all facts to support a contention of the complaint. Instead, it seeks factual information relevant to the defense that the standard of care did not require the due diligence the complaint claims.

Second, contention interrogatories are completely permissible forms of discovery.<sup>75</sup> Such interrogatories are not objectionable simply because they ask about the complaint's contentions.<sup>76</sup> The rules simply state that the Court *may* order them

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<sup>72</sup> Attached as Exhibit 12.

<sup>73</sup> *Hypertherm, Inc. v. American Torth Tip Co.*, No. 05-cv-373-JD, 2008 WL 5423833, at \*2 (D. N.H. 2008).

<sup>74</sup> *Hypertherm, Inc.*, 2008 WL 542388, at \*2.

<sup>75</sup> *Hypertherm, Inc.*, 2008 WL 542388, at \*2.

<sup>76</sup> FED. R. CIV. P. 33.

answered at some later time.<sup>77</sup> The Plaintiffs have failed to demonstrate that responses to these ROGs should be delayed any further.

These Defendants may need to seek additional discovery to rebut the PSC's responses. For example, if the PSC identifies a specific wholesaler as one who could have sold MPA to the Defendants, the Defendants may need to issue a subpoena to the wholesaler to confirm whether or not the PSC is correct. Even if the Court deems these to be contention interrogatories, they should be responded to now, particularly given the request by the PSC to rocket cases toward trial.<sup>78</sup>

**d. The PSC should be compelled to identify communications with Martin Kelvas. [ROG 7]**<sup>79</sup>

The Defendants asked the PSC to identify any communications of which the PSC was aware between the STOPNC defendants and Martin Kelvas (a former St. Thomas Hospital employee) regarding the decision to purchase medication from NECC.<sup>80</sup>

The PSC objected, saying the Defendants should already have this information. However, the PSC knows that the Defendants are not aware of any such communications because the Defendants responded to an identical interrogatory served by the PSC. The Defendants' sworn response stated that it was not aware of any such conversation. The PSC's objection is disingenuous and improper. The Plaintiffs should be compelled to respond.

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<sup>77</sup> FED. R. CIV. P. 33.

<sup>78</sup> Responses can always be supplemented if need be. See *Cytoc Corp. v. Tripath Imaging, Inc.*, No. Civ. A. 03-11142-DPW; 03-12630-DPW, 2005 WL 1527883, at \*2-\*3 (D. Mass. 2005).

<sup>79</sup> Attached as Exhibit 13.

<sup>80</sup> Mr. Kelvas is the former Director of Pharmacy at Saint Thomas Hospital. Saint Thomas Hospital is also a defendant in the suits against STOPNC. The PSC has sought to depose Mr. Kelvas and informally suggested that Mr. Kelvas has conversations with STOPNC staff about buying from compounders. To date, there has been no evidence produced to support this.

**e. The PSC should be compelled to identify admissions made by these Defendants.**  
**[ROG 5]**<sup>81</sup>

Finally, the Defendants asked the PSC to identify any statements or admissions made by these Defendants regarding their alleged negligence or the allegations of the Master Complaint. This is a standard interrogatory served (and responded to) in virtually every case. The PSC responds with nonsensical objections, including that the interrogatory requires it to review documents. This is yet another example of gamesmanship on the part of the PSC. This information is clearly discoverable. If the PSC intends to assert that an employee or agent of the Defendants admitted fault, the Defendants are entitled to know that. The PSC should be compelled to respond.

**Conclusion**

For the foregoing reasons, the Court should grant the Tennessee Clinic Defendants' Motion to Compel:

The Defendants request the following relief:

1. An order deeming the RFAs cited above admitted; or, in the alternative, an order that the Plaintiffs admit, deny, or otherwise substantively respond to the RFAs
2. An order that the Plaintiffs must respond to the interrogatories cited above
3. An order that the Plaintiffs must respond to the requests for production cited above.

**Oral Argument Requested**

The Tennessee Clinic Defendants request oral argument on this motion at the hearing before Magistrate Judge Boal on May 28, 2015, at 11:30 am EDT in Courtroom 14.

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<sup>81</sup> Attached as Exhibit 14.

**Local Rule 37.1 Certification**

Counsel for the Tennessee Clinic Defendants hereby certify that they have met and conferred with the PSC in a good-faith effort to resolve this discovery dispute. On May 6, 2015, Matt Cline for the Tennessee Clinic Defendants and Ben Gastel for the PSC conferred via phone for over an hour. Progress was made toward reaching agreement on several areas, but significant areas of dispute remain. The parties agreed that the Tennessee Clinic Defendants would proceed with filing the instant motion to ensure that it is fully-briefed by the May 28 hearing before Magistrate Judge Boal, given the current deadline for completion of common discovery. The parties also agreed to continue to work toward resolution prior to the May 28 hearing. Either in their briefing or at argument, the parties will inform the Court of any additional areas of agreement reached prior to the hearing.

Respectfully submitted,

**GIDEON, COOPER & ESSARY, PLC**

/s/ Chris J. Tardio

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***Attorneys for the Tennessee Clinic  
Defendants***

\* Admitted pursuant to MDL Order No. 1.

\*\* Admitted *pro hac vice*.

**CERTIFICATE OF SERVICE**

I hereby certify that this document filed through the CM/ECF system will be served electronically to the registered participants identified on the Notice of Electronic Filing and copies will be e-mailed or mailed via regular U.S. mail to those participants identified as unregistered this 7<sup>th</sup> day of May, 2015.

/s/ Chris J. Tardio

**Chris J. Tardio**